MEDPACE

# STATISTICAL ANALYSIS PLAN

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|---|---|
| **Protocol Title:** | A Phase 1 Dose Escalation and Expansion Study of EO-3021, an Anti-claudin 18.2 (CLDN18.2) Antibody Drug Conjugate, in Patients with Solid Tumors Likely to Express CLDN18.2 |
| **Protocol Number:** | ELVCAP-002-01 |
| **Protocol Version/Date:** | 5.0 / 06 September 2024 |
| **Investigational Product:** | EO-3021 |
| **Sponsor:** | Elevation Oncology, Inc.<br>101 Federal Street<br>Suite 1900<br>Boston, MA 02110 |
| **SAP Version/Date:** | 1.0 / 28 April 2025 |

# SIGNATURE PAGE

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We, the undersigned, have reviewed and approved this Statistical Analysis Plan:

| **Signature** | **Date** |
|---|---|
| *Electronically signed by: Aubrey Benner Reason: Approved Date: Apr 30, 2025 14:55 EDT*<br>***Aubery Benner, MPH***<br>***Statistical Scientist***<br>***Medpace, Inc.*** | |
| Juan Liang *Electronically signed by: Juan Liang Reason: Approved Date: Apr 30, 2025 13:59 EDT*<br>***Joanne Liang, PhD***<br>***Senior Director, Biostatistics***<br>***Medpace, Inc.*** | |
| *Electronically signed by: Lyon Gleich Reason: Approved Date: May 1, 2025 18:45 EDT*<br>***Lyon Gleich, MD***<br>***Sr. Vice-President, Medical Department***<br>***Medpace, Inc.*** | |
| Henry Koon MD *Electronically signed by: Henry Koon MD Reason: Approved Date: Apr 30, 2025 14:24 EDT*<br>***Henry Koon, MD***<br>***Vice President, Clinical Development***<br>***Elevation Oncology, Inc.*** | |

## VERSION HISTORY

| Version | Version Date | Description |
|---|---|---|
| 1.0 | 28 Apr 2025 | Initial draft |

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# LIST OF ABBREVIATIONS

| Abbreviation | Definition |
|---|---|
| AE | Adverse event |
| ATC | Anatomical therapeutic chemical |
| BOIN | Bayesian Optimal interval |
| BOR | Best Overall Response |
| CI | Confidence Interval |
| CR | Complete Response |
| CRF | Case report form |
| CSR | Clinical Study Report |
| CTCAE | Common Terminology Criteria for Adverse Events |
| DCR | Disease Control Rate |
| DLT | Dose Limiting Toxicities |
| DOR | Duration of response |
| EOT | End of treatment |
| GEJ | Gastroesophageal junction |
| MedDRA | Medical Dictionary for Regulatory Activities |
| NE | Non-evaluable |
| NCI | National Cancer Institute |
| ORR | Objective Response Rate |
| OS | Overall Survival |
| PD | Progressive Disease |
| PFS | Progression free survival |
| PK | Pharmacokinetics |
| PR | Partial Response |
| RDI | Relative dose intensity |
| RECIST | Response evaluation criteria in solid tumors |
| RP2D | Recommended phase 2 dose |
| SAE | Serious adverse event |
| SAP | Statistical Analysis Plan |
| SD | Stable Disease |
| SOC | System Organ Class |
| TEAE | Treatment-emergent adverse event |
| TESAE | Treatment-emergent serious adverse event |
| WHO | World Health Organization |

# 1 INTRODUCTION

The purpose of this Statistical Analysis Plan (SAP) is to provide a description of the statistical methods to be implemented for the analysis of data from the study with protocol number ELVCAP-002-01 Version 5.0 dated 06 September 2024. The SAP will be finalized prior to database lock. Any deviations from the SAP after database lock will be documented in the final Clinical Study Report (CSR).

# 2 STUDY OVERVIEW

## 2.1 Study Objectives

### *2.1.1 Primary Objective*

The primary objective of this study is to determine the recommended phase 2 dose(s) (RP2D) for the single-agent EO-3021, and when in combination with either ramucirumab or dostarlimab, for further exploration in patients with advanced/metastatic gastric/GEJ adenocarcinoma or advanced solid tumors that are likely to express CLDN18.2.

### *2.1.2 Secondary Objectives*

The secondary objectives of this study include the following:

• To document the overall safety profile for EO-3021 when administered as a single agent, and when in combination with either ramucirumab or dostarlimab

• To evaluate the PK profile of EO-3021 as a single agent, and when in combination with either ramucirumab or dostarlimab

• To assess the immunogenicity of EO-3021 as a single agent, and when in combination with either ramucirumab or dostarlimab

• To document any early indication of clinical efficacy in patients with advanced/metastatic gastric/GEJ adenocarcinoma or advanced solid tumors that are likely to express CLDN18.2 as a single agent, and when in combination with either ramucirumab or dostarlimab

### *2.1.3 Exploratory Objectives*

The exploratory objectives of this study include the following:

• To evaluate the association of anti-tumor activity of EO-3021 with CLDN18.2 expression by IHC (at various biomarker cut-offs) in advanced/metastatic gastric/GEJ adenocarcinoma or advanced solid tumors that are likely to express CLDN18.2 as a single agent, and when in combination with either ramucirumab or dostarlimab

• To evaluate if mechanistically linked biomarkers correlate with clinical outcomes as a single agent, and when in combination with either ramucirumab or dostarlimab

## 2.2 Study Design

### *2.2.1 Overview*

This Phase 1 study is a multicenter, open-label, dose escalation and expansion study conducted in patients with advanced/metastatic gastric/GEJ adenocarcinoma or advanced solid tumors that are likely to express CLDN18.2. With the release of a Protocol Administrative Letter

dated 09April2024, only patients with gastric/GEJ adenocarcinoma will be enrolled in this study. Patients with other solid tumors likely to express CLDN18.2 will be excluded from trial participation.

The study design overview is presented in Figure 1 below. The study consists of 2 parts: Part A (Dose Escalation) and Part B (Expansion).

Approximately 70 patients may be treated in Part A (Dose Escalation). Dose escalation consists of 3 arms:

- Arm A1 (monotherapy): EO-3021 as a single agent in patients with gastric/GEJ adenocarcinoma that are refractory to or intolerant of standard treatment, or for which no standard treatment is available. Dose escalation will start with EO-3021 at 1.0 mg/kg following the Bayesian Optimal interval (BOIN) design with a target DLT rate of 25% for the MTD (Yuan et al., 2016; Zhou et al., 2018). Dose escalation will proceed according to Figure 1 and Figure 2.
- Arm A2 (combination with ramucirumab): EO-3021 in combination with ramucirumab in patients with gastric/GEJ adenocarcinoma that are refractory to or intolerant of standard treatment, or for which no standard treatment is available. Combination dose escalation will start with EO-3021 at 2.0 mg/kg IV Q3W following a standard 3+3 design and proceed according to Figure 3. Ramucirumab will be administered at 10 mg/kg IV Q3W after EO-3021. The dose of Ramucirumab will be held constant while the dose of EO-3021 is escalated according to Figure 3 until RP2D/MTD is reached.
- Arm A3 (combination with dostarlimab): EO-3021 in combination with the anti-PD1 inhibitor dostarlimab in patients with gastric/GEJ adenocarcinoma that are refractory to or intolerant of standard treatment, or for which no standard treatment is available. Dose escalation will start with EO-3021 at 2.0 mg/kg IV Q3W following a standard 3+3 design and proceed according to Figure 4. Dostarlimab will be administered at 500 mg IV Q3W after EO-3021. The dose of dostarlimab will be held constant while the dose of EO-3021 is escalated according to Figure 4 until RP2D/MTD is reached.

Upon attaining an RP2D and/or MTD, Part B (Expansion) will commence in patients with gastric/GEJ adenocarcinoma. A total of approximately 120 patients could be enrolled in Part B (Expansion). The Dose Expansion cohort consists of 3 arms:

- Arm B1 (monotherapy): EO-3021 as a single agent in patients with gastric/GEJ adenocarcinoma who have received at least 1 but no more than 3 prior lines of therapy in the advanced metastatic setting. Patients will be randomized to 2.0 mg/kg or 2.5 mg/kg in a 1:1 fashion in monotherapy expansion. Prospective CLDN18.2 selection will be implemented during enrollment of the monotherapy expansion.
- Arm B2 (combination with ramucirumab): EO-3021 in combination with ramucirumab in patients with locally advanced or metastatic gastric/GEJ adenocarcinoma who previously were treated with only 1 prior line of therapy in the metastatic setting. Prior fluoropyrimidine and platinum-containing chemotherapy is required. The dose of EO-3021 will be the RP2D/MTD determined in the combination dose escalation Arm A2. Ramucirumab will be administered at 10 mg/kg IV Q3W after EO-3021. Prospective CLDN18.2 selection will be implemented during enrollment of the combination expansion.

- Arm B3 (combination with dostarlimab): EO-3021 in combination with dostarlimab in patients with locally advanced or metastatic gastric/GEJ adenocarcinoma who have not received any prior systemic therapy in the advanced metastatic setting. The dose of EO-3021 will be the RP2D/MTD determined in the combination dose escalation Arm A3. Dostarlimab will be administered at 500 mg IV Q3W after EO-3021. Prospective CLDN18.2 selection will be implemented during enrollment of the combination expansion.

**Figure 1: Study Design Overview**

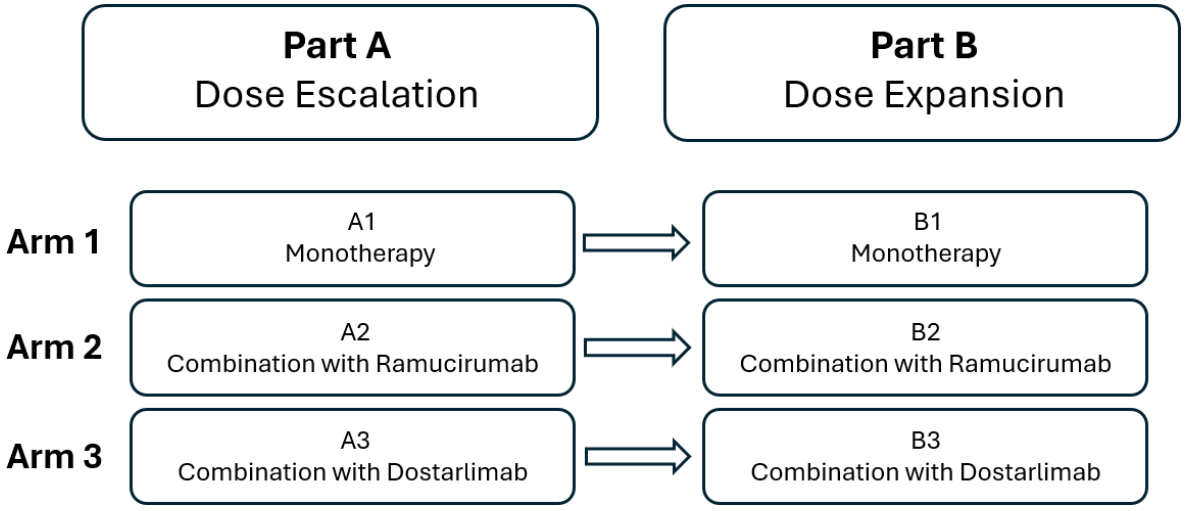
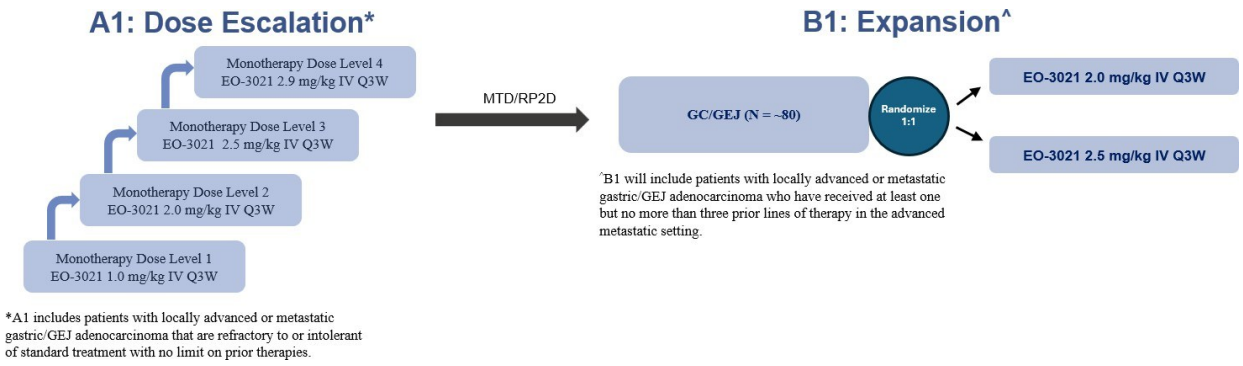
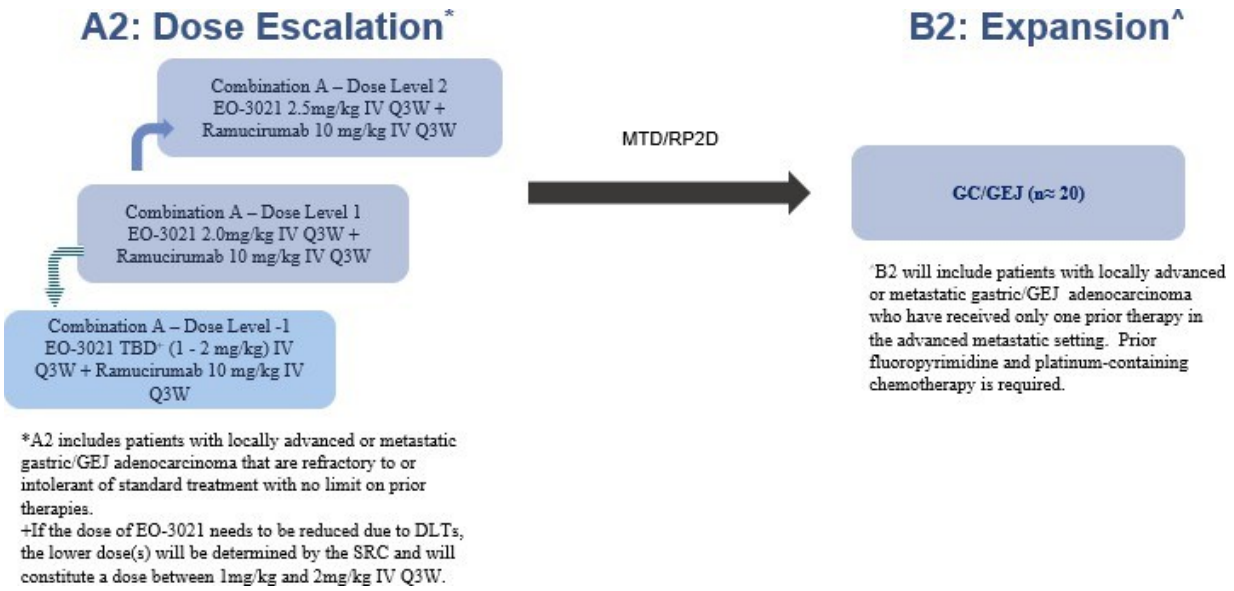



**Figure 2: Study Schema for Arm 1 (EO-3021 Monotherapy)**



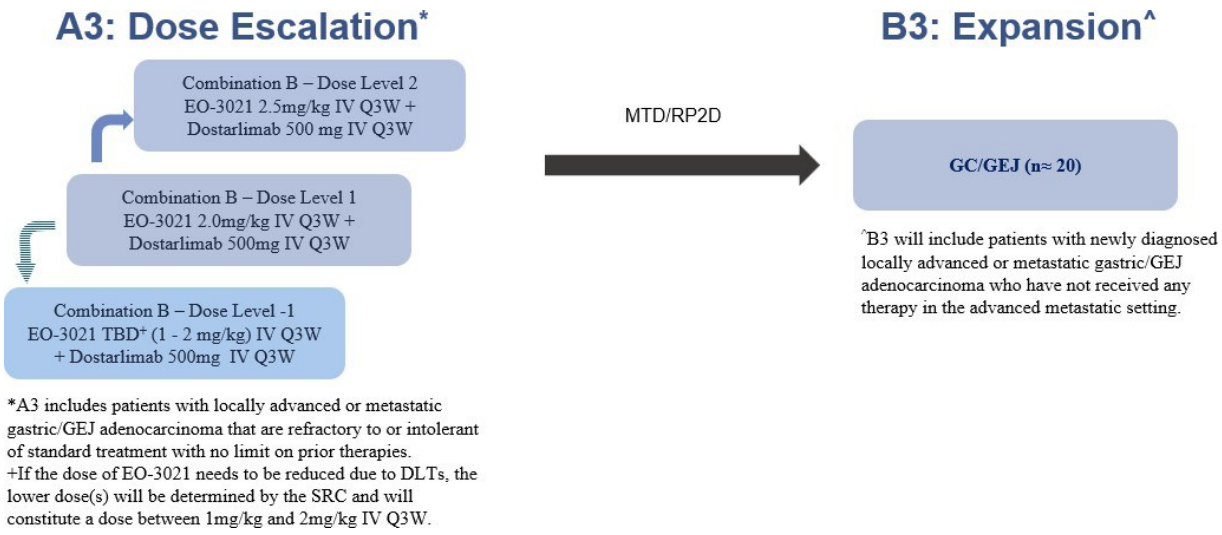

GC = Gastric cancer; GEJ = Gastro-esophageal junction; IV = Intravenous; MTD = Maximum tolerated dose; Q3W = Once every 3 weeks; RP2D = Recommended phase 2 dose

**Figure 1: Study Schema for Arm 2 (Combination with Ramucirumab)**




DLT = Dose-limiting toxicity; GC = Gastric cancer; GEJ = Gastro-esophageal junction; IV = Intravenous; MTD = Maximum tolerated dose; Q3W = Once every 3 weeks; RP2D = Recommended phase 2 dose; SRC = Safety Review Committee; TBD = to be determined

**Figure 2: Study Schema for Arm 3 (Combination with Dostarlimab)**




DLT = Dose-limiting toxicity; GC = Gastric cancer; GEJ = Gastro-esophageal junction; IV = Intravenous; MTD = Maximum tolerated dose; Q3W = Once every 3 weeks; RP2D = Recommended phase 2 dose; SRC = Safety Review Committee; TBD = to be determined

#### *2.2.2 Study Drug*

The study explores a Q3W schedule in which a dose is administered once every 3 weeks.

All patients entering this study will receive EO-3021 (alone or in combination with ramucirumab or dostarlimab) by IV infusion at a dose level based on data evaluation from the prior cohort(s). Patients should receive EO-3021 infused over 90-120 (±10) minutes for the first dose in C1D1. In the absence of infusion reactions, subsequent infusion time may gradually be decreased to 60-90 (±10) minutes, as tolerated. Longer infusion times with EO-3021 may be acceptable based on patient tolerance and adverse events. Patients in Arms A2 and B2 should receive ramucirumab infused over 60 (±10) minutes; subsequent infusion time may gradually be decreased to 30 (±10) minutes as tolerated by the patient. Patients in Arms A3 and B3 should receive dostarlimab infused over 30 (±10) minutes as tolerated by the patient. All doses should be administered on an outpatient basis. Patients will receive the protocol therapy until disease progression, unacceptable toxicity, or one or more protocol-specific treatment discontinuation criteria have been met as described in Section 6.8.1. of protocol.

#### *2.2.3 Sample Size Determination*

##### *2.2.3.1 Dose Escalation (Part A)*

The sample size during Part A (Dose Escalation) will follow the BOIN design for Arm A1 (monotherapy) and traditional 3+3 design for Arm A2 (combination with ramucirumab) and Arm A3 (combination with dostarlimab). Approximately 70 patients are expected (approximately 30 patients in Arm A1, 20 patients in Arm A2, and 20 patients in Arm A3). The actual sample size (including backfills) will depend on the number of DLTs observed and the number of doses explored.

##### *2.2.3.2 Expansion (Part B)*

For the Part B (Expansion), approximately 120 patients will be treated at the RP2D, including approximately 80 patients in Arm B1 (monotherapy) and 20 patients each in Arm B2 (combination with ramucirumab) and Arm B3 (combination with dostarlimab).

For Arm B1, the sample size is not powered based on hypothesis testing between the 2 randomized arms. It is based on practical considerations to enable the dose selection for future trials based on the totality of data involving efficacy, safety, and tolerability. With 40 patients per arm, the 95% exact Clopper-Pearson confidence intervals for ORR are calculated for the various assumed response rates (Table 1).

**Table 1: ORR and 95% Confidence Intervals Based on N=40 or 20**

| ORR (95% CI) N=40 | ORR (95% CI) N=20 |
|---|---|
| 10% (3%, 24%) | 10% (1%, 32%) |
| 20% (9%, 36%) | 20 % (6%, 44%) |
| 30% (17%, 47%) | 30% (12%, 54%) |
| 40% (25%, 57%) | 40% (19%, 64%) |

| | |
|---|---|
| 50% (34%, 66%) | 50 % (27%, 73%) |

CI = confidence interval; ORR = objective response rate

For Arms B2 and B3, 20 patients are planned for each cohort. With 20 patients per cohort, the 95% exact Clopper-Pearson confidence intervals for ORR are calculated for the various assumed response rates (Table 1).

## 2.3 Study Endpoints

### *2.3.1 Safety Endpoints*

Dose-limiting toxicities, TEAEs, serious adverse events (SAEs), vital signs, and laboratory data.

#### *2.3.1.1 Treatment-emergent Adverse Events (TEAEs)*

Adverse events (AE) will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) dictionary. Severity will be graded according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v5.0. All AEs, complaints, or symptoms that occur from the start of study treatment until 28 days after discontinuation or completion of study treatment or initiation of alternative anticancer treatment, whichever occurs first are to be recorded on the appropriate case report form (CRF).

A TEAE is defined as an adverse event that starts on or after the first administration of study medication.

#### *2.3.1.2 Dose Limiting Toxicities (DLTs)*

A DLT is defined as a TEAE that is considered at least possibly related to study treatment, occurs within the first 21 days of treatment initiation (i.e., during Cycle 1), meets at least one of the criteria listed in protocol section 6.3.4 (with severity graded according to CTCAE v5.0), and is not reasonably attributed to the patient's underlying disease or another medical condition.

Patients enrolled to backfill do not contribute to the DLT rate for the determination to escalate/de-escalate the dose level.

#### *2.3.1.3 Exposure to Study Drug*

Duration of study treatment, number of doses administered, cumulative amount of dose, and relative dose intensity will be calculated for EO-3021.

Total treatment duration:

- Total treatment duration (days) = date of last dose – date of first dose + 1
- Total treatment duration (months) = 12*Total treatment duration (days)/365.25

Relative dose intensity (RDI) is the percentage of actual dose administered relative to the intended dose planned through to treatment discontinuation.

RDI will be calculated as follows:

- RDI = 100% * d/D

where d (mg) is actual total dose administered and D (mg) is cumulative dose planned. D is the total dose that would be administered if there were no modification to dose or schedule.

#### *2.3.2 Efficacy Endpoints*

ORR (complete response [CR]+PR), DCR (CR+PR+SD), and time to event parameters (duration of response, PFS and OS)

##### *2.3.2.1 Best Overall Response (BOR)*

BOR will be summarized based on the response assessments from all visits (scheduled or unscheduled) for each patient. The BOR is defined as the best response per response evaluation criteria in solid tumors (RECIST) v1.1 in the order of CR, PR, SD, PD, non-evaluable (NE). A patient will be considered as NE for response per RECIST v1.1 at a protocol specified time point if no imaging/measurement is done or only a subset of lesion measurements is made. Confirmation scans per RECIST v1.1 must be done at least 28 days after the initial response. SD measurements must have met the SD criteria at least once after study entry at a minimum interval of 35 days.

##### *2.3.2.2 Objective Response Rate (ORR)*

ORR is defined as the proportion of patients whose overall response is a confirmed CR or PR per RECIST v1.1. To be assigned a status of confirmed PR or CR, changes in tumor measurements must be confirmed by repeated assessments at least 4 weeks (28 days) after the criteria for response are first met. Tumor assessments after the initiation of new anticancer therapy should not be used to derive the ORR.

Patients with no evaluable post-baseline disease assessments (i.e., NE) will be considered non-responders and included in the denominator in the calculation of the ORR.

##### *2.3.2.3 Disease Control Rate (DCR)*

DCR is defined as the proportion of patients with measurable disease at baseline who achieve a CR, PR, or SD per RECIST v1.1. Tumor assessments after the initiation of new anticancer therapy should not be used to derive DCR.

Patients with no evaluable post-baseline disease assessments (i.e., NE) will be considered non-responders and included in the denominator in the calculation of DCR.

#### *2.3.3 PK and ADA Endpoints*

Serum PK parameters (Cmax, AUC, t½) and ADA levels (percentage of patients developing detectable ADAs and percentage of nAbs) at prespecified time points.

# 3 STATISTICAL METHODOLOGY

## 3.1 General Considerations

In general, all analyses will be presented by study part (Part A or Part B), Arm (e.g. A1, A2, B1, etc.) and by dose levels in Part A or by randomized arm in Arm B1. Pooled safety analyses across phase and dose will also be performed for all patients treated by EO-3021 monotherapy, EO-3021 in combination with ramucirumab, EO-3021 in combination with dostarlimab, and potentially all EO-3021 treated patients as appropriate.

#### *3.1.1 Analysis Day*

Analysis day will be calculated from the date of first dose of study drug. The day of the first dose of study drug will be Day 1, and the day immediately before Day 1 will be Day -1. There will be no Day 0.

#### *3.1.2 Definition of Baseline*

Unless stated otherwise, baseline is defined as the last measurement prior to the first dose of study drug.

#### *3.1.3 Summary Statistics*

For continuous variables, descriptive summaries will include the mean, median, standard deviation, the first and third quartiles, minimum, and maximum. For categorical variables, the number and percentage of patients in each category will be presented.

#### *3.1.4 Handling of Dropouts and Missing Data*

Unrecorded data values will be recorded as missing. Only recorded (i.e., complete) data values will be used for statistical analysis. In general, invalid or missing values will not be imputed unless stated otherwise.

In cases of missing or incomplete dates (e.g., AEs and concomitant medications), the missing component(s) will be assumed as the most conservative value possible. For example, AEs with missing start dates, but with stop dates either overlapping into the treatment period or missing, will be counted as treatment-emergent, taking the worst-case approach. When partial dates are present in the data, both a partial start date and/or a partial stop date will be evaluated to determine whether it can be conclusively established that the AE started prior to the start of study drug or ended prior to the start of study drug. If the above cannot be conclusively established based on the partial and/or present dates, then the AE will be considered as treatment emergent. Actual data values as they appear in the original CRFs will be presented in the data listings.

To be conservative in the case of missing causality assessment for AEs after data querying, AEs will be assumed to be related to study drug. If the CTCAE grade is missing after data querying it will not be imputed, and the patient will be presented in table summaries based on the maximum CTCAE grade of all other recorded AEs meeting applicable criteria.

### 3.2 Analysis Populations (Sets)

Each analysis population may be further grouped by study part, arm, by dose in Part A (Dose Escalation), and by arm in Arm B1.

#### *3.2.1 Full Analysis Population*

Full Analysis Population includes all patients enrolled in the study.

#### *3.2.2 Safety Analysis Population*

Safety Analysis Population includes all patients receiving at least one dose of study treatment.

#### *3.2.3 DLT Evaluable Population*

DLT Evaluable Population includes all patients who receive at least one dose of EO-3021 and complete the DLT observation period or experience DLT(s) within the DLT observation period. DLT Evaluable Population will include Part A patients. Backfill patients are not included.

#### *3.2.4 Efficacy Evaluable Population*

Efficacy Evaluable Population includes all patients who receive at least one dose of EO-3021, have baseline measurable disease and at least one post baseline imaging assessment.

### 3.3 Patient Data and Study Conduct

#### *3.3.1 Patient Disposition*

Counts and percentages of patients who have been screened, enrolled, treated, discontinued (including reasons for discontinuation), and completed the study will be summarized.

#### *3.3.2 Protocol Deviations*

Counts and percentages of patients with CSR reportable protocol deviations by deviation category will be summarized for all enrolled patients.

#### *3.3.3 Analysis Populations*

Counts and percentages of patients in each analysis population will be summarized for all enrolled patients. Reasons for exclusion from each analysis population will also be summarized.

#### *3.3.4 Demographic and Baseline Characteristics*

The following demographic and baseline characteristics will be summarized:

- Age (years)
- Sex
- Childbearing potential
- Race
- Ethnicity
- Height (cm)
- Weight (kg)
- Body mass index (BMI) ($kg/m^2$)
- Primary tumor type

Demographic and baseline characteristics will be summarized with descriptive statistics or counts and percentages of patients for all enrolled patients.

#### *3.3.5 Concomitant Medications*

Concomitant medications will be coded to anatomical therapeutic chemical (ATC) class and preferred term using the WHO Drug Dictionary. For summary purposes, medications will be considered prior medications if they stopped prior to the first dose of study drug and concomitant medications if they were taken at any time after the first dose of study drug (i.e. started prior to the first dose of study drug and were ongoing or started after the first dose of study drug).

Counts and percentages of patients taking prior and concomitant medications by ATC class and preferred term will be summarized based on the Safety Analysis Population.

### *3.3.6 Study Drug Exposure and Compliance*

Duration of study treatment, number of doses administered, cumulative amount of dose, and relative dose intensity will be summarized descriptively for EO-3021 for monotherapy treatment arms based on the Safety Analysis Population. In addition, any modifications to the planned dose including treatment discontinuation will be summarized along with the corresponding reasons.

## 3.4 Efficacy Assessment

The primary analysis for efficacy will be based on the Efficacy Evaluable Population in Part B (Expansion) by Arm and by Arm (Arm B1 only). Sensitivity analysis may be performed based on the Full Analysis Population if it is sufficiently different from the Efficacy Evaluable Population. In addition, patients in Part A (Dose Escalation) with the same type of disease and receiving the same dose as in Part B (Expansion) may be pooled into the expansion cohort in Part B (Expansion) for a sensitivity analysis.

### *3.4.1 Objective Response Rate*

The estimate of ORR along with the Clopper-Pearson 95% confidence intervals (CIs) will be presented.

The best overall response (CR, PR, SD, PD, NE) will also be tabulated to show the number and percentage of patients in each response category.

### *3.4.2 Disease Control Rate*

The estimate of DCR along with the Clopper-Pearson 95% CIs will be presented.

## 3.5 Safety Assessment

Safety data will be summarized by actual treatment received based on the Safety Analysis Population.

### *3.5.1 Adverse Events (AEs)*

Patient incidence of all TEAEs, serious adverse events (SAEs), and treatment-related AEs will be tabulated by SOC and preferred term. All AEs are graded according to NCI-CTCAE Version 5.0. AEs by worst grade and AEs leading to treatment discontinuation will also be summarized.

An overview of AEs will be provided including counts and percentages of patients with the following:

- Any TEAEs (overall and by maximum severity)
- Any treatment-related TEAEs
- Any serious AEs (SAEs)
- Any treatment-emergent serious AEs (TESAEs)
- DLTs
- Any TEAEs leading to treatment discontinuation

- Any AEs leading to death

Counts and percentages of patients will also be presented for each of the categories in the overview.

For Part A (Dose Escalation), DLTs will be summarized based on the DLT Evaluable Population.

### *3.5.2 Clinical Laboratory Tests*

Clinical laboratory evaluations will be summarized using descriptive statistics for select laboratory parameters (e.g. chemistry, hematology, coagulation and urinalysis parameters).

Values and changes from baseline will be presented at each scheduled visit and baseline by laboratory test. Changes from baseline by scheduled time of evaluation will include EOT visit, maximum post-treatment value, and minimum post-treatment value. Both scheduled and unscheduled post-treatment visits will be considered for the summaries of the maximum and minimum post-treatment values.

## 4 CHANGES FROM PROTOCOL-SPECIFIED STATISTICAL ANALYSES

Due to the early termination of the study protocol, the following analyses will not be performed:

- Time to event analysis (DOR, PFS, OS)
- Vital signs summaries
- Electrocardiogram summaries

## 5 PROGRAMMING SPECIFICATIONS

Analyses will be performed using SAS® version 9.4 or higher. Detailed Programming Specifications will be provided in a separate document.

# 6 REFERENCES

Yuan Y, Hess KR, Hilsenbeck SG, Gilbert MR. Bayesian Optimal Interval Design: A Simple and Well-Performing Design for Phase I Oncology Trials. *Clin Cancer Res*. 2016;22(17):4291-4301. doi:10.1158/1078-0432.CCR-16-0592

Zhou H, Yuan Y, Nie L. Accuracy, Safety, and Reliability of Novel Phase I Trial Designs. Clin Cancer Res. 2018;24(18):4357-4364. doi:10.1158/1078-0432.CCR-18-0168